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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/297,701	05/05/99	DEBOUCK	C P50572

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EXAMINER	
SOUAYA, J	
ART UNIT	**PAPER NUMBER**
1655	4

DATE MAILED: 05/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/297,701	Debrouck et al
Examiner	**Group Art Unit**
Jehanne Souaya	1655

☒ Responsive to communication(s) filed on *May 5, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-22* is/are pending in the application.

Of the above, claim(s) *14-17 and 19-22* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-13 and 18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-22* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, and 18, drawn to methods of identifying genes and genes identified by the methods of claims 1-12.

Group II, claim(s) 14 and 19, drawn to proteins.

Group III, claim(s)15-17, 20-22, drawn to therapeutic compounds.

2. The inventions listed as Groups I, II, and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of groups I, II, and III are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the therapeutic agent of group III can be drawn to any compound that modulates the

activity of the protein or expression of the gene such as organic compounds, or antibodies whose structures are different than the DNA of group I or the protein of group II. Antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The products of groups I, II, and III can be used in materially different processes, for example the DNA of group I can be used in hybridization assays, the antibody of group III can be used in immunoassays, and the polypeptide of group II can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I, II, and III are patentably distinct from each other.

3. During a telephone conversation with Edward Gimme on January 5, 2000 a provisional election was made without traverse to prosecute the invention of Group I, claim 1-13 and 18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-17 and 19-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 USC § 112

Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to isolated gene sequences essential to growth of a selected organism identified by methods which were only generally described in the specification and the claims. The specification fails to provide any examples of genes identified by the methods of the claimed invention nor does the specification provide any examples of methods carried out according to the claimed invention. The claims encompass unknown gene sequences. The skilled

artisan would have no way of knowing if any gene sequence would satisfy the methods of the claimed invention because the specification fails to provide working examples of the methods of the claimed invention, the specification fails to provide any examples of gene sequences identified by the methods of the claimed invention, and has failed to provide evidence of actual reduction to practice of the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bascomb et al (EPO 0 680 722 A1) in view of Lennon et al (Trends in Genetics, October 1991, vol. 7, pp 314-317).

Bascomb teaches methods of screening for detection of herbicides (abstract) involving formation of microbes containing genes essential for plant growth and screening for compounds that inhibit plant enzymes (page 4, lines 4-5). Additionally, Bascomb teaches that once a herbicidal compound is identified, plant populations may be mutagenized an grown in the presence of the herbicide at a concentration known to be sufficient to inhibit growth of the wild type and then plants that are able to grow can be selected (page 4, lines 13-17, and lines 36-43). Bascomb teaches compositions of herbicides (page 18, lines 1-30) and isolated genes and proteins known to be essential to the growth of plants (page 2, lines 43, page 18, line 51-58).

Although Bascomb does not teach the use of a grid immobilized library to perform the screening of mutants, Lennon et al teach method of screening libraries involving generating a plurality of filters that form a grid, each grid containing at a predefined region, immobilized cDNA clones (page 314, col. 2, first para, page 315, col. 1 last para, and col. 2). Lennon also teaches the use of a "genomic" cDNA library (p. 314, col. 2, last para). Lennon teaches screening the filters with a labeled hybridization probe to, for example, identify cDNAs (equivalent to mRNAs) that are differentially expressed between tissues and/or developmental stages or directly comparing two sets of conditions (Table 1, page 316, col. 2, first full para). Lennon teaches that

the use of arrayed libraries can be used to eliminate the need for multiple rounds of clone purification, thereby improving screening methods (p 315, col. 2, last para).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the hybridization based screening method of Lennon to have screened for mutations in a population grown under defined conditions (eg. Concentration of herbicide) as taught by Bascomb to have obtained the invention as a whole. One of ordinary skill in the art at the time of the invention would have been motivated to have used the methods of Lennon for screening to have screened for herbicide resistance as taught by Bascom because Lennon teaches that the use of arrayed libraries can be used to eliminate the need for multiple rounds of clone purification, thereby improving screening methods. The ordinary artisan would have been motivated to screen for potential herbicides because Bascomb teaches such a method would be advantageous in herbicide development. Thus addition of the method of screening of Lennon to perform the method of Bascomb would have made the screening method of Bascomb easier to perform.

9. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishi et al (JBC, March 1994, vol. 269, pp 6320-6324) in view of Lennon et al (Trends in Genetics, October 1991, vol. 7, pp 314-317).

Nishi et al teaches an agent (LMB) that induces arrest of the eukaryotic cell cycle (abstract, fist para of p. 6320). Nishi teaches screening genomic library of LMB-resistant mutants

to identify the target gene of LMB (abstract, p. 6320, last para). Nishi teaches comparison of allelic mutation and wild-type (p. 6322, col. 2, fist full para). Nishi teaches the gene and protein sequence of the LMB resistant gene (p. 6322, Table II). Nishi teaches compositions of the agent LMB (figure 1).

Although Nishi does not teach the use of arid immobilized library to perform the screening of mutants, Lennon et al teach method of screening libraries involving generating a plurality of filters that form a grid, each grid containing at a predefined region, immobilized cDNA clones (page 314, col. 2, first para, page 315, col. 1 last para, and col. 2). Lennon also teaches the use of a "genomic" cDNA library (p. 314, col. 2, last para). Lennon teaches screening the filters with a labeled hybridization probe to, for example, identify cDNAs (equivalent to mRNAs) that are differentially expressed between tissues and/or developmental stages or directly comparing two sets of conditions (Table 1, page 316, col. 2, first full para). Lennon teaches that the use of arrayed libraries can be used to eliminate the need for multiple rounds of clone purification, thereby improving screening methods (p 315, col. 2, last para).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the hybridization based screening method of Lennon to have screened for LMB mutations in a population grown under defined as taught by Nishi to have obtained the invention as a whole. One of ordinary skill in the art at the time of the invention would have been motivated to have used the methods of Lennon for screening to have screened for LMB target genes as taught by Nishi because Lennon teaches that the use of arrayed libraries

can be used to eliminate the need for multiple rounds of clone purification, thereby improving screening methods. Thus addition of the method of screening of Lennon to perform the method of Bascomb would have made the screening method of Bascomb easier to perform.

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lisa B. Arthur

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800-1600

Jehanne Souaya

Jehanne Souaya
Patent examiner
May 2, 2000